K093102

5. 510(K) Summary

JUN - 8 2010

This document was prepared in accordance with 21 CFR 807.92.

Section (a)

(1) **Name of the submitter:** Nihon Seimitsu Sokki Co., Ltd.

Address of the submitter: 2508-13 Nakago, Shibukawa, Gunmma 377-0293, Japan

Telephone number of the submitter: 81-279-20-2311

Contact person: Mitsuo Kanai

Date of documentation: September 30, 2009

(2) **Trade name of the device:** Ambulatory Blood Pressure Monitor FB-270/DS-270

Common name: Ambulatory Blood pressure monitor

Classification: Class II, 74 DXN, 21 CFR 870.1130 – Cardiovascular devices panel

(3) **The predicate devices:** KOVEN AND ASSOC., INC DS-240 Ambulatory Blood pressure monitoring System, K913595

A&D Medical TM-2430 and TM 2431 Ambulatory Blood pressure monitors,K992808

(4) **Description of the device:**

Ambulatory Blood Pressure Monitor FB-270/DS-270

Ambulatory Blood Pressure Monitor FB-270/DS-270 measures highest and lowest blood pressure and heart rate, automatically at interval within 24/48 hours or manually, by its measuring algorithm written in SD card (memory card) inserted into FB-270/DS270.

The measuring algorithm is written into SD card by personal computer with specific software installed. Physicians at medical institutions will check stored data of intraday blood pressure variance in daily life on personal computer.

This device consists of Cuff main unit employing both Riva-Rocci Korotkov method and oscillometric method, and cuff unit. The cuff can be applied to upper arm circumference in range of 9.06 in. to 12.6 in. (230 mm to 320 mm) for Cuff respectively. Microphone detecting Korotkov sound is incorporated into the device. The cuff consists of pressurizing blooder and

nylon cover, and the device consists of microcomputer, event switch, pump, electronically controlled exhaust valve, microphone and indicator.

Programming to the device, readout of data measured by the device, and analysis of measurement results are executed by personal computer with exclusive analysis software BH-270 installed. Programming to SD card and readout of measured data from SD card are executed by general use memory reader.

Physicians can analyze various graphs such as trend graph, distribution map, histogram, correlation diagram displayed on PC.

(5) Intended use of the device:

Ambulatory Blood Pressure Monitor FB-270/DS-270 is intended for non-invasive continuous measurement of highest and lowest blood pressure and establishment of heart rate of adults at medical institutions.

The device functions include continuous measurement, recording and processing of measurement data.

The subject device is basically modified model of A&D Medical TM-2430 and TM 2431 Ambulatory Blood pressure monitors (510(k) No.: K992808), added with functions of KOVEN AND ASSOC., INC DS-240 Ambulatory Blood pressure monitoring System (510(k) No.: K913595).

TM-2430 and TM 2431 are portable blood pressure monitor intended for long-term, non-invasive blood pressure monitoring, in other words, measuring intraday variance of blood pressure in daily life. This intended use is the same as that of other predicate device DS-240.

Because the subject device has equivalent range of blood pressure measurement and manchette size, it can be concluded that the subject device's performance and functions are substantially equivalent to those of the predicate devices.

Though measurement time and method of processing measurement data of the subject device is different from those of the predicate devices, this does not present a new issue of safety and effectiveness.

(6) Technological characteristics of the subject device and the predicate device:

Predicate devices for determination of equivalence of technical characteristics are DS-240 Ambulatory Blood pressure monitoring System and TM-2430 and TM 2431 Ambulatory Blood pressure monitors.

Both the subject device and DS-240 employ two measuring methods, Riva-Ricci Krotkov method and oscillometric method. The only difference between them is that oscillometric method is used for DS-240 as backup only when measurement cannot be made in Riva-Ricci Korotkov method. The subject device performs measurement in both methods. TM-2430 and TM 2431 perform measurement in oscillometric method only. Because there is no technical difference of measuring algorithm and measuring accuracy, we consider clinical study made for DS-240 according to ANSI/AAMI SP10 is also applicable to the subject device.

All of above-mentioned models employ automatic air pump for pressurization. However, while initial pressurization value for the subject device can be set to any of 180,240, and 260 mmHg, that of DS-240 is 180 mmHg. If pressurization is not enough, pressurization is automatically made again with increase by 50 mmHg. TM-2430 and TM 2431 can automatically change its initial pressurization value and perform measurement. For manchette used for measurement, DS-240 has only one size, but TM-2430 and TM-2431 and the subject device can employ three different sizes of manchette, enhancing the range of arm circumference in comparison with DS-240.

These minor changes do not reduce efficiency and accuracy of measurement, but enhance them according to ANSI/AAMI Standard SP10.

Measured data is stored to SD card (the subject device), memory cassette (DS-240), and the unit itself (TM-2430 and TM 2431). Measured data can be analyzed with personal computer. These devices have different interfaces with PC. The interface with PC is Built-in SD card reader (the subject device), exclusive interface unit (DS-242 Interface unit), and RS-232C cable (TM-2430 and TM 2431). This technical difference does not present an issue affecting measurement range and accuracy.

Most remarkable technical difference is a duration of measurement (monitoring) time. DS-240 performs measurement (monitoring) for 24 hours, dividing one day into six time blocks (four hours each). For TM-2430 and TM 2431, duration of time block can be set from 15 minutes to 24 hours. The subject device can perform measurement for 48 hours and duration of time block can be set from 15 minutes to 24 hours as well as TM-2430 and TM-2431. Measurement duration is for enhancing usefulness of product, but does not affect intended use and measurement accuracy.

Generally, the subject device and predicate devices have same design concept and it does not

raise a new issue on safety and effectiveness of the subject device and affect substantial equivalence.

To determine safety and effectiveness including electrical safety, electromagnetic compatibility, clinical performance, the subject device was subjected to tests according to IEC60601-1, IEC60601-1-2, and ANSI/AAMI SP10.

Because the subject device passed the tests of these standards and met the requirements, we conclude the subject device is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUL 13 2010

Nihon Seimitsu Sokki Co. Ltd.
c/o Ms. Kyoko Arita
Cosmos Corporation
3F, 2-17-6, Akebono-cho
Tachikawa-shi
Tokyo 190-0012
JAPAN

Re: K093102
Trade/Device Name: Ambulatory Blood Pressure Monitors FB-270/DS-270
Regulatory Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II (Two)
Product Code: DXN
Dated: May 18, 2010
Received: May 24, 2010

Dear Ms. Arita:

This letter corrects our substantially equivalent letter of June 3, 2010.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K093102

1/1

510(K) Number:

Device Name: Ambulatory Blood Pressure Monitor, Model FB-270/DS-270

Indications for Use:

FB-270/DS-270 is a portable blood pressure monitor for non-invasive blood pressure measurement, monitoring intraday variance of blood pressure in daily life. They measure systolic and diastolic blood pressure and heart rate, at set interval within 24/48 hours or manually, and store the data to SD card (memory card).

The collected data can ensure the change in the day of the blood pressure in the personal computer using CD-ROM for exclusive setup.

Physicians at medical institutions will check the data on personal computer for analysis of hypertensive and hypotensive diseases.

Prescription Use ••X AND / OR Over-The Counter Use _____

(Per 21 CFR 801.109 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K093102